



November 22, 2021

Bacchus Vascular, Inc.
Bob McRae
VP, Research & Business Development
3110 Coronado Dr.
Santa Clara, California 95054

Re: K082199

Trade/Device Name: SpiralFuse Peripheral Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Bob McRae:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 17, 2008. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

**Gregory W.
O'Connell -S**

Digitally signed by
Gregory W.
O'Connell -S
Date: 2021.11.22
13:38:29 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

Bacchus Vascular, Inc.
c/o Mr. Bob McRae
3110 Coronado Drive
Santa Clara, CA 95054

Re: K082199
SpiralFuse Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: August 1, 2008
Received: August 4, 2008

Dear Mr. McRae:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

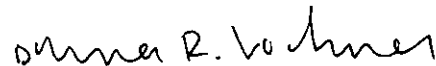
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number 800-638-2041 or 240-276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment E: Indications for Use

510(k) Number (if known): K082199

Device Name: SpiralFuse™ Peripheral Infusion System

Indications for Use: SpiralFuse Peripheral Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE -
(CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Volante
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082199

Attachment F: 510(k) Summary

OCT 17 2008

Date Prepared: June 20, 2008*General Information*

<u>Class</u>	Class II
<u>Trade Name</u>	The SpiralFuse Peripheral Infusion System
<u>Submitter</u>	Bacchus Vascular, Inc 3110 Coronado Drive Santa Clara, CA 95054 Tel: 408-980-8300 Fax: 408-980-8383
<u>Contact</u>	Bob McRae VP, Research & Business Development

Intended Use: The SpiralFuse Peripheral Infusion System is intended for controlled and selective infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature.

Predicate Device: Trellis-6 Infusion System K071664 Bacchus Vascular, Inc

Device Description: The SpiralFuse Peripheral Infusion System is a simpler version of the Trellis catheter that enables the physician to infuse fluids to a treatment region and disperse the fluid through a treatment region. The SpiralFuse is a multi-lumen catheter with an infusion lumen with holes located along the treatment zone to disperse the infused fluid. The other lumen is a through-lumen that is compatible with a 0.035" guidewire. The shaped infusion lumen is deployed once catheter position is achieved. The device is introduced through a standard 6F introducer sheath and passed over a 0.035" guidewire to the treatment site. Then, physicians will infuse fluid and allow it to disperse. Device removal is the same as the predicates.

Materials: All materials used in the manufacture of the SpiralFuse Peripheral Infusion System are suitable for this use. The materials have been used in numerous previously cleared products and confirmed biocompatible.

Testing Summary: The SpiralFuse Peripheral Infusion System was tested in the same manner as the Trellis-6. All components, subassemblies, and/or full devices met the required specifications for the completed tests.

Summary of Substantial Equivalence: The SpiralFuse Peripheral Infusion System is equivalent to the predicate product, the Trellis-6 Infusion System. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent.